Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of virtual counseling and educational booklets on self-efficacy and anxiety of mothers with premature babies discharged from the neonatal intensive care unit

Protocol summary

Study aim
Comparison of the effect of virtual counseling and educational booklet on self-efficacy and anxiety of mothers with premature babies discharged from the neonatal intensive care unit

Design
In this study, two intervention groups including virtual counseling and educational booklets and a control group with a parallel design will participate. Then, the samples will be randomly assigned to a group of 45 people for the intervention1 (receiving virtual counseling), a group of 45 for the intervention2 (receiving a training book) and a control group of 45 using 6 permutation blocks.

Settings and conduct
Mothers with premature babies discharged from the Neonatal Intensive Care Unit of Fatemieh Hospital in Hamedan who meet the inclusion criteria will be randomly allocated into three groups. The first group will receive virtual counseling, the second group will receive an educational booklet, and the third group will be the control group. Questionnaires will be completed before the intervention and 2 weeks later.

Participants/Inclusion and exclusion criteria
A healthy single baby with a birth age of 32-36 weeks

Intervention groups
Virtual consulting group: counseling sessions will be held in 4 sessions of 20-30 minutes 2 times a week with an interval of 3 days online. Educational booklet group: In this group, after completing the questionnaires at the time of discharge, the educational booklet for post-discharge care of premature babies is given to the mothers, and for 2 weeks after completing the first questionnaire, the self-efficacy and anxiety questionnaires are repeated by the people of this group. The group will be completed. Control group: In this group, the questionnaires will be completed electronically at the time of discharge and 2 weeks after that.

Main outcome variables
self-efficacy and anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221217056842N2**
Registration date: **2023-12-03, 1402/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-03, 1402/09/12**
Update count: **0**

Registration date
2023-12-03, 1402/09/12

Registrant information

Name
Mansoureh Refaei
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 81 3838 0535
Email address
mansourehrefaei@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-01, 1402/09/10

Expected recruitment end date
2024-08-31, 1403/06/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of virtual counseling and educational booklets on self-efficacy and anxiety of mothers with premature babies discharged from the neonatal intensive care unit

Public title
The effect of virtual counseling and educational booklet on self-efficacy and anxiety of mothers with premature babies discharged from hospital
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
preterm birth between 32 and 36 week singleton pregnancy Ability to read and write in persian Speaking in Persian Ability to use online software Internet access Living with spouse
Exclusion criteria:
Abnormalities in the baby Participation in training courses related to the topic of the research Medical illnesses and drug use History of any mental disorder The occurrence of unfortunate and stressful events in the last 6 months (death of relatives, divorce, serious accidents, etc.)
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **135**
Randomization (investigator's opinion)
Randomized
Randomization description
The sequence of random allocation will be determined by one of the researchers based on the permutation blocking method in three groups A, B and C using RAS(Random allocation software) software. The determined sequence will be written from beginning to end and placed in the sealed envelopes. Then, each envelope is assigned a number corresponding to the number of samples, from 1 to 135. Then the numbered envelopes are given to another researcher who is not aware of the random allocation process. Then the samples are placed in the control, virtual counseling and educational booklet groups in the order of arrival and in the order of the number of envelopes. After collecting the data, the data is entered into the software based on the number and group A, B and C. Thus the statistical analyst will not be aware of the type of assigned group.
Blinding (investigator's opinion)
Single blinded
Blinding description
After collecting the data, the data is entered into the software based on the number and group A, B and C and thus the statistical analyst will not be aware of the type of assigned group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Hamadan University Of Medical Sciences
Street address
Shahid Fahmideh Ave, Hamadan Town
City
Hamadan
Province
Hamadan
Postal code
۶۵۱۷۸۳۸۶۷۸
Approval date
2023-11-25, 1402/09/04
Ethics committee reference number
IR.UMSHA.REC.1402.563

Health conditions studied

1

Description of health condition studied
self-efficacy
ICD-10 code
ICD-10 code description

2

Description of health condition studied
anxiety
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
self-efficacy
Timepoint
Before Intervention, two weeks later
Method of measurement

Perceived Maternal Parenting Self-efficacy (PMPS-E)

2

Description
Anxietty
Timepoint
Before Intervention, two weeks later
Method of measurement
The State-Trait Anxiety Inventory (STAI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the first intervention group (virtual counseling), the time and application needed to hold virtual counseling sessions will be informed by phone. Individual counseling sessions will be held in 4 sessions of 20-30 minutes, 2 times a week with an interval of 3 days, online in the MEET application. The first counseling session will be held in the first three days after discharge (as agreed with the participant).
Category
Lifestyle

2

Description
Intervention group: In the second intervention group, after completing the questionnaires at the time of discharge, the mothers will be given a educational booklet. Self-efficacy and anxiety questionnaires will be completed again 2 weeks later by the people of this group.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Mansoureh Refaei
Street address
Pasdaran Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3828 3939
Email
mansourehrefaei@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Reza Shokoohi
Street address
Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3131 4058
Email
info.research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mansoureh Refaei
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan

Postal code
6517838695
Phone
+98 81 3838 0439
Email
mansourehrefaei@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mansoureh Refaei
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0439
Email
mansourehrefaei@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mansoureh Refaei
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Hamadan
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0439
Email
mansourehrefaei@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available